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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,159	03/26/2002	Roger Akerlund	19497-0016001 /P16512US00	2733

26191 7590 06/23/2009

FISH & RICHARDSON P.C.
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
06/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/063,159	AKERLUND ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-13,15,17-21,23-26 and 28-49* is/are pending in the application.

4a) Of the above claim(s) *2,4-7,11,18,23-25,29 and 34-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,8,10,12,13,15,17,19-21,26,28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2007 and 26 March 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage" as claimed in claim 1 and “a fluid barrier able to be ruptured by an external force is provided inside said second fluid duct” as claimed in claim 21, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Fig. 4 contains reference numbers “317” and “318” which are not found within the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 21, and consequently all dependent claims, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the limitation “a hollow spike member arranged to be retained inside walls of said inlet port and provided with a first luer-lock connector” as well as the limitation “wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage". The examiner was reviewing Fig. 5, which was the species that Applicant elected for examination on 3/23/2005, however, the Fig. 5 as amended by Applicant on 2/27/07 does not include a rupturable fluid barrier. This barrier was deleted from Figs. 4 and 5 in response to the office action mailed 11/1/06 which objected to the drawings as the barrier was not described in the specification. The examiner has also reviewed the specification and has not been able to find support for the combination of an assembly that includes a hollow spike member retained in the walls of the inlet port as well as a rupturable fluid barrier. Therefore the claimed combination of a hollow spike member retained in the walls of an inlet port and a rupturable fluid barrier is being considered new matter.

Claim 21 recites the limitation “a hollow spike that is arranged to be retained inside walls of an inlet port of a container for infusion fluid” as well as “a fluid barrier able to be rupture by an external force is provided inside said second fluid conduit”. Like

above, the examiner reviewed the amended Fig. 5 submitted by Applicant on 2/27/07 and the elected embodiment of Fig. 5 does not contain the combination of a spike inside the walls of an inlet port in addition to a rupturable fluid barrier inside the second fluid conduit. Additionally, the examiner has not been able to find support such combination in the specification. Therefore the claimed combination of a hollow spike member retained in the walls of an inlet port and a rupturable fluid barrier is being considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "said second fluid duct" in the last line of claim 21. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 26, 28, 30, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarrow (US Patent No. 5,061,264). Scarrow discloses a drug container (48) comprising: a fixed dose of a medical substance, and a cap (20) for sealing said drug container (Fig. 1 discloses that the cap is perfectly capable of sealing the drug container), said cap further comprising a luer lock connector (32; col. 3, lines 37-38 disclose that portion 32 is the connector that connects with luer lock connector 16) for attachment to a corresponding connector (16) provided on an inlet port (12) of a container for infusion fluid (10), thereby creating a luer lock coupling.

In reference to claim 26, Scarrow discloses a pierceable closure (72) for protecting said second luer lock connector (72 is perfectly capable of protecting the luer lock connector (32) from anything that may enter from the open end of 46).

In reference to claim 28, Scarrow discloses that the drug container further comprise an opening sealed by a closure (60), and said cap further comprises a hollow needle (70) for penetrating said closure.

In reference to claim 30, Scarrow discloses that the drug container further comprises a neck (58), said cap further comprises a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector, and said cap further comprising locking members (locking members 140 and 141 work together to grasp the neck of the drug container; also see col. 5, line 60 through col. 6, line 3) for grasping said neck.

In reference to claim 32, Scarrow discloses that the cap further comprises a protruding member (28) forming a fluid duct between said drug container and said luer

lock connector, wherein a fluid barrier is provided inside said fluid duct (rupturable barrier 74 is within 28, as 28 extends all the way into the cap portion to where 74 is located), said drug container comprising a rigid material (col. 3, line 65 discloses the drug container is glass), said protruding member comprising a more flexible material than said luer lock connector and said drug container, and said fluid barrier is made of a more brittle material than said drug container (col. 4, lines 41-42)., said protruding portion, and said luer lock connector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 8, 10, 12, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow (US Patent No. 5,061,264) in view of Shemesh et al. (US Patent No. 5,817,083). Scarrow discloses the device substantially as claimed

including: a fluid transfer assembly (Fig. 1) for use in an infusion system, said assembly comprising: a fluid container (10) having an infusion fluid, a drug container (48) having a medical substance, at least one fluid barrier (74 and 14) controlling fluid passage between said drug container and said fluid container, said fluid container further comprising at least one inlet port (12) for receiving said medical substance from said drug container, said drug container further comprising a cap (20) for sealing said drug container, said at least one inlet port further comprising a first luer lock connector (16; col. 3, line 14), and said cap further comprising a second luer lock connector (32; col. 3, lines 37-38 disclose that portion 32 is the connector that connects with luer lock connector 16) for attachment to said first luer lock connector, wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage (col. 3, line 27; col. 4, lines 41-42). Scarrow, however, does not disclose that the walls of the inlet port are made of flexible material or that the fluid transfer assembly comprises a first clamping member to compress the walls. Shemesh, however, discloses a similar device (Fig. 1) with an inlet port (14) with walls made of a flexible material and which are able to be compressed by a first clamping member (24) in order to close the first fluid duct formed and prevent undesired fluid passage between the fluid container and the first luer lock connector. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Scarrow with the flexible walls and clamp, as taught by Shemesh, in order to provide a device that has fluid flow that can be easily controlled during the fluid transfer procedure.

In reference to claim 3, Scarrow discloses that the cap further comprises a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector, wherein said fluid barrier is provided inside said second fluid duct (rupturable barrier 74 is within 28, as 28 extends all the way into the cap portion to where 74 is located).

In reference to claim 8, Scarrow discloses that the second luer lock connector further comprises a pierceable closure (72) for protection before use.

In reference to claim 10, Scarrow discloses that the drug container further comprises an opening sealed by a closure (60), and said cap further comprising a hollow needle (70) for penetrating said closure.

In reference to claim 12, Scarrow discloses that the drug container further comprises a neck (58), said cap further comprising a protruding member (28) forming a second fluid duct between said drug container and said second luer-lock connector, and said cap further comprising locking members (fig. 10 discloses locking members 140 and 141 work together to grasp the neck; also see col. 5, line 60 through col. 6, line 3) for grasping said neck.

In reference to claim 16, Scarrow discloses that the fluid container further comprises a protruding resilient tube (12 protrudes externally from the inside of the fluid container), said first luer lock connector (16) of said at least one inlet port being provided on a hollow spike member (spike part of 14) able to be firmly retained inside said tube.

In reference to claim 19, Scarrow discloses that the cap further comprises a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector, said fluid barrier being provided inside said second fluid duct (rupturable barrier 74 is within 28, as 28 extends all the way into the cap portion to where 74 is located), said drug container comprising a rigid material (col. 3, line 65), said protruding member comprising a more flexible material than said second luer connector and said drug container, and said fluid barrier comprising a more brittle material than said drug container, said protruding portion, and said second luer lock connector (col. 4, lines 41-42).

In reference to claim 20, Scarrow discloses that the composition of said drug container is selected from the group consisting of glass and a rigid polymer material (col. 3, line 65 discloses the drug container is glass).

Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow (US Patent No. 5,061,264) in view of Shemesh et al. (US Patent No. 5,817,083) and further in view of Haber et al. (US Patent No. 5,593,028). Scarrow in view of Shemesh discloses the device substantially as claimed including a fluid barrier (74), however, Scarrow does not disclose that the barrier is a brittle polymer. Haber, however, discloses a rupturable barrier comprises of a brittle polymer dividable along a weakening line by said external force (col. 7, lines 5-16). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified

Scarrow in view of Shemesh with the brittle barrier, as taught by Haber, in order to provide a barrier that is assured to break upon the external force applied, in order to assure that the flow between containers takes place during a critical medical infusion to a patient.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow (US Patent No. 5,061,264) in view of Shemesh et al. (US Patent No. 5,817,083) and further in view of Vaillancourt (US Patent No. 5,897,526). Scarrow in view of Shemesh discloses the device substantially as claimed including a protruding member (28) forming a second fluid duct between said drug container and said second luer lock connector and an inlet port (12). However, Scarrow in view of Shemesh does not disclose a clamping members or an infusion line. Vaillancourt, however, discloses a clamping members (Fig. 14, 22' and 55) as well as an infusion line (12) attached to the inlet port. The clamping members could be used on the neck portion of (28) to compress the protruding member, thereby closing said second fluid duct and preventing undesirable fluid passage between said second luer lock connector and said drug container, and the infusion line could be used at the inlet port to allow the medication/fluid to be infused into the patient. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Scarrow in view of Shemesh with the clamping members and infusion line, as taught by Vaillancourt, in order to provide a means for delivering the medication as well as to

provide a means for stopping flow in the even that flow between the drug container and the fluid container needs to be suddenly stopped.

Response to Arguments

Applicant's arguments filed 3/23/2009 have been fully considered but they are not persuasive. Upon reviewing the amendment submitted in addition to the specification and the drawings, the examiner has determined that the claimed combination is not present within the application as originally filed and therefore is being considered new matter. Please see the new matter rejection above. Until the new matter situation is sorted out and the examiner is able to understand what exactly is being claimed, the examiner will be maintaining the previous art rejection under the Scarrow, Shemesh, Haber and Vaillancourt references.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767